



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1179]

Request for Nominations for Voting and/or Nonvoting Consumer Representatives on Public Advisory Committees or Panels and Request for Notification from Consumer Organizations Interested in Participating in the Selection Process for Nominations for Voting and/or Nonvoting Consumer Representatives on Public Advisory Committees or Panels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Nominees recommended to serve as a voting or nonvoting consumer representative may be self-nominated or may be nominated by a consumer organization. Nominations will be accepted for current vacancies and for those that will or may occur through December 2014.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests on an FDA advisory committee or panel may send a letter or email stating that interest to the FDA (see ADDRESSES) by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see ADDRESSES) by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process and consumer representative nominations should submit their information electronically to kimberly.hamilton@fda.hhs.gov or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993-0002, FAX 301-847-8640.

Consumer representative nominations should be submitted electronically by logging into the FDA advisory Committee Membership Nomination Portal at <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993-0002, or by fax to 301-847-8640. Additional information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

FOR FURTHER GENERAL INFORMATION CONTACT: Kimberly Hamilton, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5117, Silver Spring, MD 20993-0002, 301-796-6319, email: kimberly.hamilton@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

For questions relating to specific advisory committees or panels, contact the following persons listed in table 1:

Table 1.--Advisory Committee Contacts

| Contact Person | Committee/Panel |
|--|--|
| Jamie Waterhouse, Center for Devices and Radiological Health, Office of Device Evaluation, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1611, Silver Spring, MD 20993, 301-796-3063, FAX: 301-796-3063, email: Jamie.Waterhouse@fda.hhs.gov . | Circulatory System Devices Panel |
| Karen Strambler, Center for Food Safety and Applied Nutrition, FDA College Park, CPK1, rm. 1C016, College Park, MD 20740, 240-402-2589, FAX: 301-436-2637, email: Karen.Strambler@fda.hhs.gov . | Food Advisory Committee |
| Patricio Garcia, Center for Devices and Radiological Health, Office of Device Evaluation, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3631, Silver Spring, MD 20903, 301-796-6875, FAX: 301-847-8120, email: Patricio.Garcia@fda.hhs.gov . | General and Plastic Surgery Devices Panel |
| Sara J. Anderson, LCDR, U.S. Public Health Service, Center for Devices and Radiological Health, Office of Device Evaluation, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1643, Silver Spring, MD 20903, 301-796-7047, FAX: 301-847-8122, email: Sara.Anderson@fda.hhs.gov . | Hematology and Pathology Devices Panel, Orthopaedic and Rehabilitation Devices Panel, National Mammography and Quality Assurance Advisory Committee. |
| Pamela Scott, Center for Devices and Radiological Health, Office of the Center Director, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3611, Silver Spring, MD 20993, 301-796-5433, FAX: 301-847-8510, email: Pamela.Scott@fda.hhs.gov . | Medical Devices Dispute Resolution Panel |
| Shanika Craig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1613, Silver Spring, MD 20993-0002, 301-796-6639, FAX: 301-847-8122, email: Shanika.Craig@fda.hhs.gov . | Obstetrics and Gynecology Devices Panel |
| Walter Ellenberg, Office of the Commissioner, Office of Pediatric Therapeutics, Food and Drug Administration, Bldg. 32, rm. 5154, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-0885, FAX: 301-847-8640, email: Walter.Ellenberg@fda.hhs.gov . | Pediatrics Advisory Committee |
| Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2438, Silver Spring, MD 20993-0002, 301-796-9005, FAX: 301-847-8533, email: Kalyani.Bhatt@fda.hhs.gov . | Psychopharmacologic Drugs Advisory Committee, Reproductive Health Drugs Advisory Committee |

FDA is requesting nominations for voting and/or nonvoting consumer representatives for the vacancies listed in table 2:

Table 2.--Committee Descriptions, Type of Consumer Representative Vacancy and Approximate Date Needed

| Committee/Panel/Areas of Expertise Needed | Current & Upcoming Vacancies | Approximate Date Needed |
|---|------------------------------|-------------------------|
| Circulatory System Devices--Knowledgeable in the safety and effectiveness of marked and investigational devices for use in the circulatory and vascular systems. | Nonvoting | Immediately |
| Food Advisory Committee--Knowledgeable in the fields of physical sciences, biological and life sciences, food science, risk assessment, nutrition, food technology, molecular biology, and other relevant scientific and technical disciplines. | Voting | Immediately |
| General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee--Knowledgeable in the fields of general, plastic, reconstructive, pediatric, thoracic, abdominal, pelvic and endoscopic surgery; biomaterials, lasers, wound healing, and quality of life issues. | 1-Nonvoting | 9/1/2014 |
| Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee--Knowledgeable in the fields of hematology, hematopathology, coagulation and homeostasis, hematological oncology, and gynecological oncology. | 1-Nonvoting | Immediately |
| Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee--Knowledgeable experts with broad, cross-cutting scientific, clinical, analytical, or mediation skills. | 1-Nonvoting | 10/1/2014 |
| National Mammography Quality Assurance Advisory Committee--Knowledgeable in clinical practice, research specialization, or professional work that has a significant focus on mammography. | 1-Nonvoting | |
| Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee--Knowledgeable in the fields of perinatology, embryology, reproductive endocrinology, pediatric gynecology, gynecological oncology, operative hysteroscopy, pelviscopy, electrosurgery, laser surgery, assisted reproductive technologies, contraception, postoperative adhesions, and cervical cancer and colposcopy; obstetrics/gynecology devices; gynecology in the older patient; midwifery; labor and delivery nursing. | 1-Nonvoting | Immediately |
| Orthopaedic and Rehabilitation Devices Panel--Knowledgeable in data concerning the safety and effectiveness of marketed and investigational orthopaedic and rehabilitation devices. | 1-Nonvoting | Immediately |
| Pediatrics Advisory Committee--Knowledgeable in pediatric research, pediatric subspecialties, statistics, and/or biomedical ethics. | 1- Voting | Immediately |
| Psychopharmacologic Drugs Advisory Committee--Knowledgeable in the fields of psychopharmacology, psychiatry, epidemiology or statistics, and related specialties. | 1- Voting | Immediately |
| Bone, Reproductive, and Urologic Drugs Advisory Committee--Knowledgeable in the fields of obstetrics, gynecology, endocrinology, pediatrics, epidemiology, or statistics and related specialties. | 1- Voting | Immediately |

I. Functions

A. Certain Panels of the Medical Devices Advisory Committee

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions the Federal Food, Drug, and Cosmetic Act (the FD&C Act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of devices into one of three regulatory categories, advises on any possible risks to health associated with the use of devices, advises on formulation of product development protocols, reviews premarket approval applications for medical devices, reviews guidelines and guidance documents, recommends exemption of certain devices from the application of portions of the FD&C Act, advises on the necessity to ban a device, and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

B. Food Advisory Committee

The Committee provides advice to the Commissioner of Food and Drugs and other appropriate officials, on emerging food safety, food science, nutrition, and other food-related health issues that the FDA considers of primary importance for its food and cosmetics programs. The Committee may be charged with reviewing and evaluating available data and making

recommendations on matters such as those relating to: (1) Broad scientific and technical food or cosmetic related issues; (2) the safety of new foods and food ingredients; (3) labeling of foods and cosmetics; (4) nutrient needs and nutritional adequacy; and (5) safe exposure limits for food contaminants. The Committee may also be asked to provide advice and make recommendations on ways of communicating to the public the potential risks associated with these issues and on approaches that might be considered for addressing the issues.

C. National Mammography and Quality Assurance Advisory Committee

The Committee reviews and evaluates: (1) Developing appropriate quality standards and regulations for mammography facilities; (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (3) developing regulations with respect to sanctions; (4) developing procedures for monitoring compliance with standards; (5) establishing a mechanism to investigate consumer complaints; (6) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities; (7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (9) determining the costs and benefits of compliance with these requirements.

D. Pediatric Advisory Committee

The Committee advises and makes recommendations to the Commissioner of Food and Drugs regarding: (1) Pediatric research; (2) identification of research priorities related to pediatric therapeutics and the need for additional treatments of specific pediatric diseases or conditions; (3) the ethics, design, and analysis of clinical trials related to pediatric therapeutics; (4) pediatric

labeling disputes; (5) pediatric labeling changes; (6) adverse event reports for drugs granted pediatric exclusivity and any safety issues that may occur' (7) any other pediatric issue or pediatric labeling dispute involving FDA regulated products; (8) research involving children as subjects; and (9) any other matter involving pediatrics for which FDA has regulatory responsibility. The Committee also advises and makes recommendations to the Secretary directly or to the Secretary through the Commissioner on research involving children as subjects that is conducted or supported by the Department of Health and Human Services.

E. Psychopharmacologic Drugs Advisory Committee

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the practice of psychiatry and related fields.

F. Bone, Reproductive, and Urologic Drugs Advisory Committee

Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology, and related specialties.

G. The Medical Devices Dispute Resolution Panel

The Panel provides advice to the Commissioner on complex or contested scientific issues between the FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The Panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

II. Criteria for Members

Persons nominated for membership as consumer representatives on committees or panels should meet the following criteria: (1) Demonstrate ties to consumer and community-based organizations; (2) be able to analyze technical data; (3) understand research design; (4) discuss benefits and risks; and (5) evaluate the safety and efficacy of products under review. The consumer representative should be able to represent the consumer perspective on issues and actions before the advisory committee, serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations, and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

III. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests should send a letter stating that interest to FDA (see ADDRESSES) within 30 days of publication of this document.

Within the subsequent 30 days, FDA will compile a list of consumer organizations that will participate in the selection process and will forward to each such organization a ballot listing at least two qualified nominees selected by the Agency based on the nominations received, together with each nominee's current curriculum vitae or résumé. Ballots are to be filled out and returned to FDA within 30 days. The nominee receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee or panel.

IV. Nomination Procedures

Any interested person or organization may nominate one or more qualified persons to represent consumer interests on the Agency's advisory committees or panels. Self-nominations are also accepted. Nominations should include a cover letter and a current curriculum vitae or résumé for each nominee, including a current business and/or home address, telephone number, email address if available, and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations should also specify the advisory committee(s) or panel(s) for which the nominee is recommended. In addition, nominations should include confirmation that the nominee is aware of the nomination, unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest. Members will be invited to serve for terms up to 4 years.

FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. Upon selecting qualified nominees for the ballot, FDA will provide those consumer organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate themselves to serve as voting or nonvoting consumer representatives will not participate in the selection process.

Dated: August 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-19696 Filed 08/19/2014 at 8:45 am; Publication Date: 08/20/2014]